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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/885,259	02/23/2001	Madhav N. Devalaraja	PC18174A	3713

7590 09/10/2002

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EXAMINER	
BELYAVSKYI, MICHAIL A	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 09/10/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/885,259	DEVALARAJA ET AL.	
	Examiner	Art Unit	
	Michail A Belyavskyi	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire.SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 July 2001 and 15 May 2002* .

2a)☒ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-33* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *restriction/Election Rax* .

DETAILED ACTION

1. Applicant's amendment filed 07/09/2001 (Paper No 2) is acknowledged.

Claims 1-33 are pending.

Restriction Requirement

2. Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula Hutzell, Ph.D., Supervisory Patent Examiner at Paula.Hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

3. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-5, 7 and 11, drawn to an inhibitor of colony stimulating factor (CSF), wherein the CSF is a M-CSF, comprising an agent which binds to M-CSF or antibody directed to M-CSF and a pharmaceutical composition comprising said inhibitor, classified in Class 530, subclasses 350 and 387.1

II. Claims 1-5, 7 and 11, drawn to an inhibitor of colony stimulating factor (CSF), wherein the CSF is a M-CSF, comprising an agent which inhibits expression of a M-CSF, and a pharmaceutical composition comprising said inhibitor classified in Class 530, subclass 350.

III. Claims 1-5, 7 and 11, drawn to an inhibitor of colony stimulating factor (CSF), wherein the CSF is a M-CSF, comprising an agent which is an antagonist of a colony stimulating factor receptor (M-CSFR), or antibody directed to M-CSFR and a pharmaceutical composition comprising said inhibitor classified in Class 530, subclasses 350 and 387.1

IV. Claims 1-5, 7 and 11, drawn to an inhibitor of colony stimulating factor (CSF), wherein the CSF is a M-CSF, comprising an agent which inhibits activation of a M-CSFR, and a pharmaceutical composition comprising said inhibitor classified in Class 530, subclass 530.

V Claims 1, 3, 6-9 and 11, drawn to an inhibitor of colony stimulating factor (CSF), wherein the CSF is a G-CSF, comprising an agent which binds to G-CSF, or antibody directed to G-CSF and a pharmaceutical composition comprising said inhibitor, classified in Class 530, subclasses 350 and 387.1

VI. Claims 1, 3, 6-9 and 11, drawn to an inhibitor of colony stimulating factor (CSF), wherein the CSF is a G-CSF, comprising an agent which inhibits expression of a G-CSF, and a pharmaceutical composition comprising said inhibitor classified in Class 530, subclass 350.

VII. Claims 1, 3,6-9 and 11, drawn to an inhibitor of colony stimulating factor (CSF), wherein the CSF is a G-CSF, comprising an agent which is an antagonist of a colony stimulating factor receptor (G-CSFR), or an antibody directed to G-CSFR and a pharmaceutical composition comprising said inhibitor classified in Class 530, subclasses 350 and 387.1.

VIII. Claims 1, 3, 6-9 and 11, drawn to an inhibitor of colony stimulating factor (CSF), wherein the CSF is a G-CSF, comprising an agent which inhibits activation of a G-CSFR, and a pharmaceutical composition comprising said inhibitor classified in Class 530, subclass 530.

IX. Claims 1, 3,7, 10 and 11, drawn to an inhibitor of colony stimulating factor (CSF), wherein the CSF is a GM-CSF, comprising an agent which binds to GM-CSF, or antibody directed to GM-CSF and a pharmaceutical composition, comprising said inhibitor, classified in Class 530, subclasses 350 and 387.1.

X. Claims 1, 3, 7, 10 and 11, drawn to an inhibitor of colony stimulating factor (CSF), wherein the CSF is a GM-CSF, comprising an agent which inhibits expression of a GM-CSF, and a pharmaceutical composition comprising said inhibitor classified in Class 530, subclass 350.

XI. Claims 1, 3, 7, 10 and 11, drawn to an inhibitor of colony stimulating factor (CSF), wherein the CSF is a GM-CSF, comprising an agent which is an antagonist of a colony stimulating factor receptor (GM-CSFR), or antibody directed to GM-CSFR and a pharmaceutical composition comprising said inhibitor classified in Class 530, subclasses 350 and 387.1.

XII. Claims 1, 3, 7, 10 and 11, drawn to an inhibitor of colony stimulating factor (CSF), wherein the CSF is a GM-CSF, comprising an agent which inhibits activation of a GM-CSFR, and a pharmaceutical composition comprising said inhibitor classified in Class 530, subclass 530.

XIII Claims 12 , 14, 31-33 drawn to a method of treating inflammation, comprising administering an inhibitor, classified in Class 424 , subclasses 130.1, 184.1.

XIV. Claims 12 and 17, drawn to a method of treating osteoporosis, comprising administering an inhibitor, classified in Class 424 , subclasses 130.1, 184.1.

XV. Claims 12 , 15, 16, 18 and 19, drawn to a method of treating an autoimmune disease, comprising administering an inhibitor, classified in Class 424 , subclasses 130.1, 184.1.

XVI. Claims 12 and 13 drawn to a method of treating atherosclerosis, comprising administering an inhibitor, classified in Class 424 , subclasses 130.1, 184.1.

XVII. Claims 20 –24 , drawn to a method for screening for an inhibitor of a M-CSF using a fluorescent Activated Cell Sorter technique, classified in Class 435, subclass 7.1.

XVIII. Claims 25-26 , drawn to a method for screening for an inhibitor of a G-CSF, classified in Class 435, subclass 7.1.

XIX. Claim 27 , drawn to a method for screening for an inhibitor of a GM-CSF, classified in Class 435, subclass 7.1.

XX. Claim 28, drawn to a method for screening for an inhibitor of a CSF, classified in Class 435, subclass 7.1.

XXI. Claims 29-30, drawn to a method for screening for an inhibitor of a M-CSF comprising measuring binding of an (I^{125}) M-CSF to an M-CSFR, classified in Class 435, subclass 7.1.

4. Groups I -XII are different products. An agent which binds to CSF, an agent which inhibits expression of CSF, an antagonist of CSFR, an antibody to CSF or CSFR, an agent which inhibits activation of a CSFR and pharmaceutically acceptable salt differ with respect to their structures and physicochemical properties and mode of action, therefore each product is patentably distinct.

5. Groups XIII-XXI are different methods. The inventions as grouped in Groups XXII -XXX are distinct, each from the other, because they are different with respect to ingredients, method steps, and endpoints; therefore, each method is patentably distinct.

6. Groups I -XII and Groups XIII-XVI are related as product and process of using. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)).

In the instant case, the agent which binds to CSF, an agent which inhibits expression of CSF, an antagonist of CSFR, an agent which inhibits activation of a CSFR can be used as an immunogen to produce antibodies as well as in the therapeutic methods claimed; an antibody to CSF or CSFR can be used to detect or to purify antigens of interest as well as the therapeutic methods claimed. Therefore they are patentably distinct.

7. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct method steps. Moreover, a prior art search also requires a literature search. It is an undue burden for the examiner to search more than one invention. Therefore restriction for examination purposes as indicated is proper.

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskyi whose telephone number is (703) 308-4232. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Michail Belyavskyi, Ph.D.
Patent Examiner
Technology Center 1600
September 9, 2002

CHRISTINA CHAN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600